

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. 2002F–0220]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Acesulfame Potassium

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of acesulfame potassium (ACK) as a general-purpose sweetener and flavor enhancer in food, not including meat and poultry. This action is in response to a food additive petition filed by Nutrinova, Inc. It will simplify the existing regulations by replacing all of the currently listed uses of ACK with a single-use category for food.

DATES: This rule is effective [*insert date of publication in the Federal Register*]. Submit written or electronic objections and requests for a hearing by [*insert date 30 days after date of publication in the Federal Register*].

ADDRESSES: Submit written objections and requests for a hearing to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic objections at <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Blondell Anderson, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 202–418–3106.

SUPPLEMENTARY INFORMATION:**I. Background**

In a notice published in the **Federal Register** on May 20, 2002 (67 FR 35552), FDA announced that Nutrinova, Inc., 285 Davidson Ave., suite 102, Somerset, NJ 08873, had filed a food additive petition (FAP 2A4735). The petition proposed to amend § 172.800 *Acesulfame potassium* (21 CFR 172.800) to provide for the safe use of ACK as a general-purpose sweetener and flavor enhancer.

ACK is currently approved under § 172.800 for use in 12 food categories at levels determined by current good manufacturing practice. The existing regulation has resulted from the approval of seven food additive petitions (FAPs). The practical effect of the amendment requested in the current petition would be to broaden the regulation to include any additional food category not allowed by the current regulation, with the exception, as discussed in the following paragraphs, of meat and poultry, and to replace the 12 currently listed uses of ACK with a single-use category for food.

The acceptable daily intake (ADI) of 15 milligrams per kilogram body weight per day (mg/kg bw/d) or 900 mg per person per day (mg/p/d) was established for ACK as a result of FDA's review of FAP 2A3659 (53 FR 28379, July 28, 1988), which resulted in the agency's initial approval of ACK in several food categories. The ADI is the level of consumption that has been determined to be safe for human consumption every day over an entire lifetime. The present petition does not contain any new information that would cause FDA to alter this previously determined ADI for ACK.

FDA's review of the petitions submitted subsequent to FAP 2A3659 involved primarily the following factors: (1) An assessment of the estimated

exposure from each additional use; and (2) a determination of whether the cumulative estimated exposure, including the newly requested use, would cause the ADI for ACK to be exceeded over a lifetime by individuals who consume ACK at high levels. In its evaluation of ACK for use in nonalcoholic beverages, including beverage bases, FDA also assessed the safety from exposure to acetoacetamide-N-sulfonic acid (AAS) and acetoacetamide (AAA), the two principal hydrolysis products of ACK (63 FR 36344 at 36346 to 36355, July 6, 1998).

Although the functionality of ACK was addressed in earlier FAPs, in the current petition, Nutrinova, Inc., provided the results from taste panel studies demonstrating the sweetness profile of ACK as a function of concentration in a variety of foods. These data demonstrate that ACK can be used alone or in blends with other intense sweeteners or bulk sweeteners (e.g., sucrose) at self-limiting levels depending on the food application (Ref. 1).

II. Determination of Safety

Under the general safety standard provisions of section 409(c)(3)(A) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)(A)), a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. FDA's food additive regulations (21 CFR 170.3(i)) define safe as a "reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use."

The food additives anticancer, or Delaney, clause (section 409(c)(3)(A) of the act) further provides that no food additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal. Importantly, however, the Delaney clause applies to the additive itself and not to

constituents of the additive. Thus, where an additive has not been shown to cause cancer, even though it contains a carcinogenic impurity, the additive is not subject to the legal effect of the Delaney clause. Rather, the additive is properly evaluated under the general safety standard using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the proposed use of the additive (*Scott v. FDA*, 728 F.2d 322 (6th Cir. 1984)).

III. Evaluation of Safety for the Petitioned Uses of the Food Additive

To determine whether ACK can be safely used as a general-purpose sweetener and flavor enhancer, FDA focused its evaluation on whether human exposure to ACK from these uses would exceed the ADI of 15 mg/kg bw/d, and on the potential health risk from exposure to the primary hydrolysis products, AAS and AAA, and the impurity, methylene chloride.

A. Exposure to ACK, AAS, and AAA

FDA has determined the cumulative estimated daily intake (CEDI) for ACK from its use as a general-purpose sweetener and flavor enhancer in food for eaters-only at the 90th percentile intake to be 313 mg/p/d (Refs. 2 and 3). This CEDI is based on the following factors: (1) The amount of ACK that may be used in the currently regulated food categories and (2) the maximum use level of ACK in other representative food categories in which the sweetener may be used. FDA concludes that the updated CEDI for ACK is well below the ADI (900 mg/p/d). FDA has determined that the updated CEDIs for AAS and AAA are 250 micrograms per person per day ($\mu\text{g/p/day}$) and 0.36 $\mu\text{g/p/day}$, respectively (Refs. 1 and 3). These hydrolysis products are formed only under extreme conditions of temperature and/or pH. The agency has determined that

the increase in exposure to AAS and AAA, due to the additional uses, is negligible and does not pose any safety concerns (Refs. 3, 4, and 5).

B. Methylene Chloride

Methylene chloride, a carcinogenic chemical, is a potential impurity in ACK resulting from its use as a solvent in the initial manufacturing step of the sweetener. Data previously submitted in FAP 0A4212 show that methylene chloride could not be detected in the final product at a limit of detection (LOD) of 40 parts per billion (ppb) as discussed in the July 6, 1998, final rule (63 FR 36344 at 36346). In the past, FDA has assumed that methylene chloride is present in ACK at the LOD of 40 ppb (worst-case scenario) and has evaluated its safety by performing a risk assessment for methylene chloride based on this level. No new information has been received to change FDA's previous risk assessment for methylene chloride. Moreover, FDA does not expect that methylene chloride will be present in ACK due to the following factors: (1) The multi-step purification process used in the manufacture of ACK and (2) the volatility of methylene chloride (Ref. 1).

IV. Conclusion

FDA has reviewed the information available in its files on ACK and its hydrolysis products, as well as the current petition, and concludes that there is a reasonable certainty that no harm will result from the use of ACK as a general-purpose sweetener and flavor enhancer in foods. However, in accordance with a memorandum of understanding between the Food Safety and Inspection Service (FSIS), United States Department of Agriculture, and FDA (65 FR 51758, August 25, 2000), a restriction from use "in meat and poultry" is included in the ACK regulation. This restriction is applied when the petitioner does not specify that the food additive is intended for such use.

At this time, FSIS has not evaluated data on the suitability of use of ACK in meat or poultry. Therefore, FDA concludes that the food additive regulations should be amended as set forth in this document.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person. As provided in § 171.1(h), FDA will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

V. Environmental Effects

FDA has carefully considered the potential environmental effects of this action. FDA concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. FDA's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

VI. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VII. Objections

Any person who will be adversely affected by this regulation may at any time file with the Division of Dockets Management (see **ADDRESSES**) written or electronic objections on or before *[insert date 30 days after date of publication in the **Federal Register**]*. Each objection shall be separately

numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

VIII. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum from D. Robie, Division of Petition Review, Chemistry Review Group, to B. Anderson, Division of Petition Review, Regulatory Group II, October 7, 2002, and addendum memorandum from S. E. Carberry, Division of Petition Review, Chemistry Review Group, to B. Anderson, Division of Petition Review, Regulatory Group I, August 28, 2003.

2. Memorandum from D. Robie, Division of Petition Review, Chemistry Review Group to B. Anderson, Division of Petition Review, Regulatory Group II, March 19, 2003, and addendum memorandum from S. E. Carberry, Division of Petition Review,

Chemistry Review Group, to B. Anderson, Division of Petition Review, Regulatory Group I, August 28, 2003.

3. Memorandum to the file, July 7, 2003.

4. Memorandum from M. Bleiberg, Division of Petition Review, Toxicology Review Group I, to B. Anderson, Division of Petition Review, Regulatory Group I, December 18, 2002.

5. Memorandum from M. Bleiberg, Division of Petition Review, Toxicology Review Group I, to B. Anderson, Division of Petition Review, Regulatory Group II, April 2, 2003.

List of Subjects in 21 CFR Part 172

Food additives, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

■ 1. The authority citation for 21 CFR Part 172 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

■ 2. Section 172.800 is amended by revising the introductory paragraph and paragraph (c), and by removing paragraphs (d) and (e) to read as follows:

§ 172.800 Acesulfame potassium.

Acesulfame potassium (CAS Reg. No. 55589–62–3), also known as acesulfame K, may be safely used as a general-purpose sweetener and flavor enhancer in foods generally, except in meat and poultry, in accordance with current good manufacturing practice and in an amount not to exceed that

reasonably required to accomplish the intended technical effect in foods for which standards of identity established under section 401 of the Federal Food, Drug, and Cosmetic Act do not preclude such use, under the following conditions:

(a) * * *

(b) * * *

(c) If the food containing the additive is represented to be for special dietary uses, it shall be labeled in compliance with part 105 of this chapter.

Dated: December 17, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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